

REMARKS

Status of the Claims.

Claims 1, 13-17, 19, 20, 24-27, 48, 50-52, and 54 are pending with entry of this amendment, claims 2-12, 18, 21-23, 28-47, 49, and 53 being cancelled and no claims being added herein. Claims 1, 13, 14, 16, 17, 24, 26, 48, and 50 are amended herein. These amendments introduce no new matter. Support is replete throughout the specification and claims (e.g., in the claims as originally filed).

Election/Restriction.

Claim 54 was withdrawn from consideration because according to the Examiner, the elected invention was limited to composition comprising a targeting moiety comprising SEQ ID NO:61 and newly added claim 54 is drawn to a fusion peptide comprising SEQ ID NO:60. Applicants traverse.

Contrary to the Examiner's assertion, however, **claim 54 is drawn to a composition comprising the fusion peptide having an amino acid sequence of SEQ ID NO:70, not SEQ ID NO:60.**

Inspection of the sequence listing shows that SEQ ID NO:70 has the sequence:

Lys Lys His Arg Lys His Arg Lys His Arg Lys His
Gly Gly Ser Gly Gly Ser Lys Asn Leu Arg Arg Ile
Ile Arg Lys Gly Ile His Ile Ile Lys Lys Tyr Gly

of which the first 12 amino acids are the sequence of SEQ ID NO:61. Withdrawal of claim 54 from consideration is thus improper. Claim 54 is within the elected group and should be examined on the merits.

35 U.S.C. §112, Second Paragraph.

The rejection of claims 1-2, 24, and 47-53 under 35 U.S.C. §112, second paragraph, as allegedly indefinite because the claims were allegedly drawn to non-elected inventions was maintained.

The claims, as amended herein, are directed to a composition comprising "... a targeting moiety comprising the amino acid sequence K-K-H-R-K-H-R-K-H-R-K-H (SEQ ID NO:61) ...". The pending claims are thus within the elected group and the rejection under 35 U.S.C. §112, second paragraph, on these grounds should be withdrawn.

Claim 1 was rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite in the use of the phrase "specifically killing microbial organisms". Claim 1 is amended herein to eliminate the "specifically killing" language and to simply recite "[a] composition for killing microbial organisms ...", thereby obviating this rejection.

Claim 24 was rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite in the recitation of the phrase "... wherein the target microbial organism is *Pseudomonas*". Claim 24 is amended herein to recite "... wherein the target microbial organism is a member of the genus *Pseudomonas* ..." thereby obviating this rejection.

35 U.S.C. §112, First Paragraph.

Claims 1-2, 10-11, 13-20, 24-25, and 47-53 were rejected under 35 U.S.C. §112, first paragraph, as set forth in the previous office action. In particular, the Examiner alleged that the claims required that the composition "specifically kill" the target organism and alleged the specification fails to disclose methods of identifying targeting moieties that bind only to one specific organism. Applicants traverse.

The claims, as amended herein, are directed to a composition comprising: "... a targeting moiety comprising the amino acid sequence K-K-H-R-K-H-R-K-H-R-K-H (SEQ ID NO:61) attached to an antimicrobial peptide moiety ...". The specification clearly teaches that this targeting moiety binds to a microbial organism. The specification further teaches that an antimicrobial peptide attached to the targeting moiety will kill the target microbial organism. One of skill reading the specification would recognize that other antimicrobial peptides attached to the targeting moiety would also kill the target (bound) microbial organisms.

Moreover, the Examiner is reminded that claims directed to a particular antibody attached to an "effector" (e.g., a cytotoxin) are routinely allowed by the Patent Office.

The Examiner is also reminded that to be enabling under §112, first paragraph, a patent must contain a description that enables one skilled in the art to make and use the claimed invention.

That some experimentation is necessary does not constitute a lack of enablement; the amount of experimentation, however, must not be unduly extensive.

Whether undue experimentation is required by one skilled in the art is typically determined by reference to eight factors considered relevant to the inquiry: (1) quantity of experimentation necessary; (2) amount of guidance presented; (3) presence of working examples; (4) nature of the invention; (5) state of the prior art; (6) relative skill of those in the art; (7) predictability of the art; and (8) breadth of the claims. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) citing *Ex parte Forman Inc.*, 230 USPQ 546 (BPAI 1986). In the instant case, Applicants explain below that the practice of the pending claims does not require undue experimentation.

Given the claimed invention is directed to a particular targeting moiety attached to an anti-microbial peptide, relatively little experimentation (Wands Factor 1) is required. Moreover, considerable guidance (Wands Factor 2) with respect to anti-microbial peptides and their attachment to the targeting moiety as well as working examples (Wands Factor 3) are provided. The nature of the invention (Wands Factor 4) is relatively straightforward. One of skill reading the specification would readily recognize that a number of different antimicrobial peptides could be attached to the targeting moiety recited in the claim and provide effective killing. The prior art (Wands Factor 5) with respect to targeted killing moieties (*e.g.*, antibody-targeted cytotoxins) is well developed. The relative skill of those in the art (Wands Factor 6) is high (typically Ph.D.). Moreover given the recitation in the claims of the targeting sequence, the predictability of the art (Wands Factor 7) is high and the breadth of the claims (Wands Factor 8) is narrow.

Thus, when viewed in light of the factors enumerated in *Wands*, the claimed invention does not require undue experimentation and the rejection of the claims under 35 U.S.C. §112, first paragraph, should be withdrawn.

Claims 1, 24-27, and 49-53 were rejected under 35 U.S.C. §112, first paragraph, as allegedly introducing new matter. In particular, the Examiner alleged that the phrase "wherein the targeting moiety is fused in-frame with the anti-microbial peptide . . ." only appears in the specification, or original claims as filed with regard to the targeting moiety being a peptide.

In the claims as amended herein the targeting moiety is always a peptide. Accordingly the "fused in-frame" phrase does not introduce new matter and the rejection on these grounds should be withdrawn.

Claims 1-2, 10-11, 13-20, 24-27, and 47-53 were rejected under 35 U.S.C. §112, first paragraph, as allegedly introducing new matter. In particular the Examiner alleged that the phrase "specifically killing microbial organisms . . ." only appears in the specification, or original claims as filed with regard to the fusion protein G10Cato and does not provide support for the full breadth of the rejected claims. While applicants disagree with the Examiner's position, to expedite prosecution, the phrase "specifically killing microbial organisms. . ." is eliminated with entry of the present amendment thereby obviating this rejection. Please note, however, that Applicants reserve the right to file subsequent applications claiming the amended out subject matter and the amendment should not be construed as abandonment or agreement with the Examiner's position in the Office Action.

35 U.S.C. §§102/103.

Claims 1-2, 10-11, 13-20, 24-27, and 47-53 were rejected under 35 U.S.C. §102(b) allegedly anticipated by or, in the alternative under 35 U.S.C. §103(a) as obvious in light of Goldenberg (U.S. Patent 5,332,627). (For the purpose of this response, Applicants assume the Examiner meant Goldenberg (US Patent 5,332,567)). Applicants traverse.

The pending claims are directed to:

1. A composition for killing microbial organisms said composition comprising:
a targeting moiety comprising the amino acid sequence K-K-H-R-K-H-R-K-H-R-K-H (SEQ ID NO:61) attached to an antimicrobial peptide moiety, where said targeting moiety binds to a target microbial organism and whereby said composition has an antimicrobial effect on said target microbial organism. [emphasis added]

The targeting moiety is clearly not an antibody.

In contrast, Goldenberg describes **conjugates comprising antibodies** or antibody fragments:

The present invention resolves many of the problems involved in the treatment of infections that are refractive to conventional drug therapy **by using very specific antibodies made against microbial or parasitic antigens in order to target an effective radionuclide and/or chemical agent to foci of infection**, thereby selectively killing the pathogen. [emphasis added] (col. 3, lines 41-46)

Goldenberg fails to disclose any composition comprising "... a targeting moiety comprising the amino acid sequence K-K-H-R-K-H-R-K-H-R-K-H (SEQ ID NO:61) ..." as recited in the pending claims and thus fails to anticipate the presently claimed invention. Accordingly the rejection under 35 U.S.C. §102(b) should be withdrawn.

In addition, Goldenberg offers no teaching or suggestion of a composition comprising "... a targeting moiety comprising the amino acid sequence K-K-H-R-K-H-R-K-H-R-K-H (SEQ ID NO:61) ...". To the contrary, in teaching the use of antibodies to target therapeutics to microbial or parasitic antigens, Goldenberg effectively leads one of skill away from compositions comprising the targeting moiety recited in the presently pending claims. Goldenberg thus teaches away from the presently claimed invention and the rejection under 35 U.S.C. §103(a) should be withdrawn.

Obviousness-Type Double Patenting.

Claim 2 was provisionally rejected under the judicially created doctrine of obviousness-type double patenting in light of claims 12 and 13 of copending Application No: 10/077,624.

Applicants note that this is a provisional obviousness-type double patenting rejection. Accordingly, no action is required at this time.

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (415)576-0200.

Respectfully submitted,

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